



1556 04 APR 15 14:23

## INDEPENDENT BAKERS ASSOCIATION

P.O. Box 3731 • Washington, DC 20027 • (202) 333-8190 • Fax (202) 337-3809

[www.independentbaker.org](http://www.independentbaker.org)

April 15, 2004

Division of Dockets Management (HFA-305)

Food & Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

Re: Docket Number 2003N-0076; Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Reopening of Comment Period (March 1, 2004)

Dear Sir or Madam:

The Independent Bakers Association (IBA) submits the following comments on the docket referenced above. IBA is a wholesale baking trade association comprising of over four hundred domestic and international members who are responsible for approximately one-half of U.S. baked goods production. Members include small to medium-sized wholesale bakers, and other allied trades and groups related to the baking industry, such as suppliers, manufacturers, education centers, and other associations.

IBA's comments are focused on FDA's consideration of additional trans fat labeling requirements, beyond the quantitative disclosure mandated by the July 2003 Final Rule. The March 1 Notice indicates that such additional labeling requirements could take the form of a new Daily Value (either a trans fat DV or a combined trans fat/saturated fat DV) or a footnote or disclosure statement about trans fat.

IBA supports the declaration of trans fat on a separate line in the nutrition facts label, as prescribed in the July 2003 Final Rule. In addition, we strongly believe that

there is no sound basis for requiring additional trans fat labeling at the present time. IBA's rationale for this view is discussed below, beginning with some important background information.

### **Background**

FDA is of course aware that some baked products contain trans fatty acids from partially hydrogenated vegetable oils. In considering the issues surrounding trans fat and baked goods, it is important to understand the history of how partially hydrogenated vegetable oils came to be used in baked goods, and the practical alternatives to those oils that currently exist.

In the 1970's and 1980's, partially hydrogenated vegetable oils were thought to be much healthier than oils that are high in saturated fat. Consequently, many bakers replaced oils such as palm oil, coconut oil, beef tallow or lard with partially hydrogenated vegetable oils in product formulations. Bakers were able to use partially hydrogenated oils in lieu of the more saturated alternatives because they provided acceptable baking functionality, shelf life, and product taste and texture.

Since that time, the scientific evidence has changed, and now there is evidence that trans fat raises LDL cholesterol and total blood cholesterol. Accordingly, bakers are working to reformulate products to lower trans fat levels by reducing or eliminating the partially hydrogenated vegetable oil content. However, in the case of some baked goods, currently the only practical alternatives to partially hydrogenated oils are oils that are high in saturated fat. Thus, for those products, a reduction in trans fat would be accompanied by an increase in saturated fat. Further, in some instances, the amount of saturated fat added would have to exceed the amount of trans fat removed.

The media "hype" regarding trans fat generally does not take into account those practical reformulation issues. It appears that some activist groups are attempting to characterize partially hydrogenated oils as "poison." Some of their statements suggest to consumers that the food industry should immediately remove all trans fat from processed foods, regardless of the accompanying increase in saturated fat. The available scientific evidence does not support that position.

Some organizations and media reports have referred to trans fat as the "stealth" fat or the "hidden" fat, as if the food industry chose to use partially hydrogenated vegetable oils and purposely hide the trans fat content. The fact is, as discussed above, the evidence regarding the physiological effects of trans fat has changed since the time hydrogenated oils were introduced; and labeling regulations have not required or even allowed food manufacturers to declare trans fat content. This mischaracterization of the food industry's intentions has fed what seems to be undue attention to trans fat, such that the Agency is considering extraordinary precedents in nutrition labeling.

It is important to keep in mind that, despite all the attention given to trans fat recently, consumption of saturated fat in the U.S. is much greater than that of trans fat,

and there is little doubt that saturated fat consumption is the greater public health concern. We urge FDA to maintain a balanced, science-based approach to these matters.

It seems to us that the current initiative to consider more trans fat labeling requirements—coming as it does less than a year after the July 2003 Final Rule—may in part be a reaction to the media/activist "hype." In our view, FDA should maintain the nutrition facts label format prescribed in the July 2003 Final Rule. Mandating additional trans fat labeling requirements at this time would not be in the best interests of consumers or the food industry. A detailed explanation of our position on these issues follows.

### **FDA Should Not Establish a DV for Trans Fat**

#### **No New Scientific Evidence**

In the July 2003 Final Rule, after a rulemaking process that lasted over three and one-half years, FDA determined that the scientific evidence was not sufficient to support establishment of a DV for trans fat. Accordingly, FDA declined to adopt a DV. There has been no material change in the scientific evidence since July 2003, and consequently at this point we do not believe FDA should reverse its decision.

FDA's March 1 Notice cited the December 2003 report of the Institute of Medicine/National Academy of Sciences (IOM/NAS) as a factor in FDA's decision to reconsider adopting a DV for trans fat. That report proposed a novel and unprecedented methodology for establishing a trans fat DV (and new DVs for saturated fat and cholesterol).

The methodology suggested in the December 2003 IOM/NAS report differs greatly from the methodology used by FDA in establishing the existing DVs. The existing DVs are based on "quantitative dietary intake recommendations developed from extensive scientific evidence . . . ." (See Preamble to July 2003 Final Rule, 68 FR at 41456.) The recent IOM/NAS report did not supply such quantitative recommendations with respect to trans fat.

Instead, that report suggests using food consumption data, data from dietary surveys, and menu modeling to establish a DV. IBA understands that, currently, food consumption data and dietary survey data regarding trans fat are very limited and probably are not sufficient for the purpose contemplated by IOM/NAS. Menu modeling can feasibly achieve any arbitrary DV in a targeted range; however, IBA does not believe there is a scientific justification for that approach.

Employing the methodology described in the December 2003 IOM/NAS report to establish a trans fat DV would be an extreme departure from FDA's past practice, and that report does not provide an appropriate foundation for such a DV.

## NLEA Requirements

IBA understands that some comments have argued that the Nutrition Labeling and Education Act of 1990 ("NLEA") requires FDA to establish a DV for trans fat. IBA strongly disagrees with that suggestion.

NLEA directed that FDA devise a label format to serve two overall purposes: 1) to allow consumers to make product to product comparisons, and 2) to allow consumers to make judgments about how a single product fits into the diet. However, NLEA did not mandate adoption of the % DV format, and certainly did not mandate establishment of a DV for every nutrient. We note in this regard that there are other nutrients, such as sugars, for which FDA has not adopted a DV.

As discussed above, currently there is insufficient scientific evidence to support establishment of a trans fat DV. Clearly the NLEA's drafters did not intend to require the establishment of a DV under such circumstances.

## Questions About the % DV Format

It is also important to point out that the efficacy of the % DV format has recently been called into question. For example, FDA's own research in the "Calories Count" report of the Working Group on Obesity (2004) found that "(V)ery few participants reported using the % DV column on the NFP. Either they did not understand the meaning of % DV or they thought that it was not relevant to them since they did not consume a 2000 calorie diet." ([www.fda.gov/oc/initiatives/obesity](http://www.fda.gov/oc/initiatives/obesity)) This behavioral research indicates that the % DV format does little to help consumers determine how products fit in the context of a daily diet.

## FDA Should Not Adopt a Combined Trans Fat/Saturated Fat DV

The December 2003 IOM/NAS report recommended that FDA adopt a combined DV for trans fat and saturated fat. In the prior rulemaking FDA rejected that approach, and we urge FDA not to change its position on this question.

By adopting a combined trans fat/saturated fat DV, FDA would be creating a "cholesterol-raising fat" category on the nutrition facts label. We believe that establishing such a labeling category (or any labeling category based on a physiological indicator) is unwarranted.

As discussed in the preamble to the July 2003 Final Rule, the concept of a label based on physiological indicators, rather than the traditional chemical definitions, presents many problems. (See, e.g., 68 FR at 41453 and 41454.) One critical problem with that approach is that the significance of physiological indicators changes over time. Nutrition science is far from static, and scientific understanding of the effects of nutrients

on human health will continue to evolve in the future. Distinct chemical definitions, on the other hand, are not subject to such changes.<sup>111</sup>

Maintaining separate trans fat and saturated fat categories will limit the nutrition facts panel to objective, factual information, and will help promote consumer confidence in its reliability. This format will also easily accommodate future scientific developments, and help to ensure that scientific debate over the relative effects of trans fats and other fatty acids takes place outside the context of the nutrition label. (See Comments of the Staff of the Bureau of Economics and Consumer Protection of the Federal Trade Commission, April 17, 2000)

### **FDA Should Not Adopt a Footnote or Disclosure Statement**

#### **Regarding Trans Fat**

IBA does not support the footnote/disclosure statement approach to trans fat labeling. IBA's reasons for this position are set forth in our comments on the prior rulemaking (comment number C2284, dated December 16, 2002). Those comments are incorporated herein by reference.

As discussed in our prior comments, we believe that the nutrition label should provide factual, product-specific information. Broader dietary guidance is more effectively provided through the activities of public and private health and nutrition education programs.

#### **Timing, Costs, and Related Considerations**

The July 2003 Final Rule mandates the quantitative declaration of trans fat content, on a separate line in the nutrition facts panel. Food manufacturers are in the process of adding that information to their labels. All labels must comply with the new requirements by January 1, 2006.

Thus, consumers will be able to compare the trans fat content, of different products, and to make purchase decisions based on trans fat content if that information is important to their individual dietary needs. Importantly, the July 2003 Final Rule maintains the appearance of the nutrition label with which consumers are already familiar. Consumer understanding and awareness will be further enhanced by the FDA web site which has an excellent educational section about trans fat and the new food label.

In the preamble to the July 2003 Final Rule, FDA stated that consumer knowledge of trans fat will improve as more dietary recommendations are made for limiting trans fat

and as trans fat is included in nutrition labeling. (See 68 FR at 41453.) IBA agrees with that assessment which militates against the adoption of additional labeling requirements at this time.

Manufacturers are incurring substantial costs to bring their labels into compliance with the July 2003 Final Rule. Additional trans fat labeling requirements would subject manufacturers to additional costs, without corresponding benefit to consumers.

IBA also notes that the DVs for many nutrients may change as a result of recommendations in the IOM/NAS (2002) macronutrient report, and that other labeling changes may be considered as a result of the initiatives FDA's Working Group on Obesity. These potential changes should be considered and evaluated in one rulemaking. The piecemeal approach being contemplated, which would involve a series of changes to the nutrition label, would undermine consumer confidence in the label. Further, the piecemeal approach would impose an unreasonable cost burden on the food industry.

FDA should also consider the findings regarding cholesterol contained in the Summary of Data Accomplishments from the National Health and Nutrition Examination Surveys (NHANES). ([www.cdc.gov/nchs/about/major/nhanes/DataAccomp.htm](http://www.cdc.gov/nchs/about/major/nhanes/DataAccomp.htm).) That report shows that blood cholesterol levels are not rising, and have apparently not risen in conjunction with the food industry's use of partially hydrogenated oil products. The report states: "Today, people routinely keep an eye on their cholesterol. When NHANES started testing, one-third of adults had high cholesterol. Today fewer than 1 in 5 adults has high cholesterol." These NHANES findings cast further doubt on the merits of pursuing additional trans fat labeling at this time.

IBA appreciates the opportunity to provide input on this matter of great importance to the baking industry. Any questions regarding our comments should be directed to the undersigned.

Sincerely,



Nicholas A. Pyle, President

Independent Bakers Association